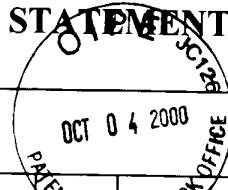


**INFORMATION
DISCLOSURE
STATEMENT**


| | |
|---------------------------------|------------------------|
| Atty. Docket No.: 235.0020 0101 | Serial No.: 09/518,156 |
| | |
| Applicant(s): TARLETON et al. | |
| Filing Date: 2 March 2000 | Group: Unassigned |

U.S. PATENT DOCUMENTS

| Examiner Initial | PATENT & TRADEMARK OFFICE | Document Number | Date | Name | Class | SubClass | Filing Date If Appropriate |
|------------------|---------------------------|-----------------|------|------|-------|----------|----------------------------|
| | | NONE | | | | | |

FOREIGN PATENT DOCUMENTS

| | | Document Number | Date | Country | Class | SubClass | Translation |
|--|--|-----------------|------|---------|-------|----------|-------------|
| | | | | | | | Yes |
| | | NONE | | | | | No |

OTHER DOCUMENTS (Including Authors, Title, Date, Pertinent Papers, etc.)

| | | |
|--|--|--|
| | | Armah et al., "S-Myristoylation of a Glycosylphosphatidylinositol-specific Phospholipase C in <i>Trypanosoma brucei</i> ," <i>J. Biol. Chem.</i> , 274(9):5931-5938 (February 26, 1999). |
| | | Abrahamsohn, "Cytokines in innate and acquired immunity to <i>Trypanosoma cruzi</i> infection," <i>Braz. J. Med. Biol. Res.</i> , 31(1):117-121 (January 1998). |
| | | Alberti et al., "Specific cellular and humoral immune response in Balb/c mice immunised with an expression genomic library of <i>Trypanosoma cruzi</i> ," <i>Vaccine</i> , 16(6):608-612 (April 1998). |
| | | Al-Qahtani et al., "A 5' untranslated region which directs accurate and robust translation by prokaryotic and mammalian ribosomes," <i>Nuc. Acids Res.</i> , 24(6):1173-1174 (1996). |
| | | Andrews et al., "Presence of antibodies to the major surface glycoprotein of <i>Trypanosoma cruzi</i> amastigotes in sera from chagasic patients," <i>Am. J. Trop. Med. Hyg.</i> , 40(1):46-49 (1989). |
| | | Andrews, "The Acid-Active Hemolysin of <i>Trypanosoma cruzi</i> ," <i>Exp. Parasitol.</i> , 71:241-244 (1990). |
| | | Barry et al., "Protection against mycoplasma infection using expression-library immunization," <i>Nature</i> , 377(6550):632-635 (1995). |
| | | Barry et al., "Biological features of genetic immunization," <i>Vaccine</i> , 15(8):788-791 (1997). |
| | | Basombrio, " <i>Trypanosoma cruzi</i> : Partial Prevention of the Natural Infection of Guinea Pigs with a Killed Parasite Vaccine," <i>Exp. Parasitol.</i> , 71:1-8 (1990). |

| EXAMINER | Date Considered |
|---|-----------------|
| *Examiner: Initial if reference considered, whether or not citation is in conformance with MPEP 609; Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant. | |

| | | |
|---|---------------------------------|------------------------|
| INFORMATION DISCLOSURE STATEMENT <i>OCT 04 2000</i> <i>PATENT & TRADEMARK OFFICE</i> | Atty. Docket No.: 235.0020 0101 | Serial No.: 09/518,156 |
| | | |
| | Applicant(s): TARLETON et al. | |
| | Filing Date: 2 March 2000 | Group: Unassigned |

| | | |
|--|--|--|
| | | Bharadwaj et al., "Induction of Protective Immune Responses by Immunization with Linear Multiepitope Peptides Based on Conserved Sequences from <i>Plasmodium falciparum</i> Antigens," <i>Infect. Immun.</i> , <u>66</u> (7):3232-3241 (July 1998). |
| | | Biebinger et al., "A Plasmid Shuttle Vector Bearing an rRNA Promoter is Extrachromosomally Maintained in <i>Critchidia fasciculata</i> ," <i>Exp. Parasitol.</i> , <u>83</u> (2):252-258 (1996). |
| | | Bliss et al., "IL-12, as an Adjuvant, Promotes a T Helper 1 Cell, but Does Not Suppress a T Helper 2 Cell Recall Response," <i>J. Immunol.</i> , <u>156</u> :(3):887-894 (1996). |
| | | Brener, "Why Vaccines do not work in Chagas Disease," <i>Parasitol. Today</i> , <u>2</u> (7):196-197 (1986). |
| | | Carpenter et al., "Linearized free maxicircle DNA in <i>Critchidia fasciculata</i> is a product of topoisomerase II-mediated cleavage," <i>Mol. Biochem. Parasitol.</i> , <u>76</u> :115-123 (1996). |
| | | Chow et al., "Development of Th1 and Th2 Populations and the Nature of Immune Responses to Hepatitis B Virus DNA Vaccines Can Be Modulated by Codelivery of Various Cytokine Genes," <i>J. Immunol.</i> , <u>160</u> (3):1320-1329 (February 1, 1998). |
| | | Clayton et al., "Protein Trafficking in Kinetoplastid Protozoa," <i>Microbiol. Rev.</i> , <u>59</u> (3):325-344 (1995). |
| | | Coburn et al., "Stable DNA transfection of a wide range of trypanosomatids," <i>Mol. Biochem. Parasitol.</i> , <u>46</u> :169-179 (1991). |
| | | Conry et al., "Polynucleotide-Mediated Immunization Therapy of Cancer," <i>Seminars Oncol.</i> , <u>23</u> (1):135-147 (1996). |
| | | Costa et al., "Immunization with a plasmid DNA containing the gene of <i>trans</i> -sialidase reduces <i>Trypanosoma cruzi</i> infection in mice," <i>Vaccine</i> , <u>16</u> (8):768-774 (May 1998). |
| | | Cross et al., "The Surface <i>Trans</i> -Sialidase Family of <i>Trypanosoma Cruzi</i> ," <i>Ann. Rev. Microbiol.</i> , <u>47</u> :385-411 (1993). |
| | | DeRisi et al., "Use of a cDNA microarray to analyse gene expression patterns in human cancer," <i>Nature Genet.</i> , <u>14</u> (4):457-460 (1996). |
| | | DeRisi et al., "Exploring the Metabolic and Genetic Control of Gene Expression on a Genomic Scale," <i>Science</i> , <u>278</u> (5338):680-686 (1997). |

| | |
|-----------------|------------------------|
| EXAMINER | Date Considered |
|-----------------|------------------------|

*Examiner: Initial if reference considered, whether or not citation is in conformance with MPEP 609; Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

| | | |
|---|---------------------------------|------------------------|
| INFORMATION DISCLOSURE STATEMENT <i>OCT 04 2000</i> | Atty. Docket No.: 235.0020 0101 | Serial No.: 09/518,156 |
| | | |
| | Applicant(s): TARLETON et al. | |
| | Filing Date: 2 March 2000 | Group: Unassigned |

| | | |
|--|--|---|
| | | Donnelly et al., "DNA Vaccines," <i>Ann. Rev. Immunol.</i> , 15 :617-648 (1997). |
| | | Endresz et al., "Induction of human cytomegalovirus (HCMV)-glycoprotein B (gB)-specific neutralizing antibody and phosphoprotein 65 (pp65)-specific cytotoxic T lymphocyte responses by naked DNA immunization," <i>Vaccine</i> , 17 (1):50-58 (January 1999). |
| | | Englund, "The structure and biosynthesis of glycosyl phosphatidylinositol protein anchors," <i>Annu. Rev. Biochem.</i> , 62 :121-138 (1993). |
| | | Freedman et al., "Two more independent selectable markers for stable transfection of <i>Leishmania</i> ," <i>Mol. Biochem. Parasitol.</i> , 62 :37-44 (1993). |
| | | Fontt et al., "Relationship between granulocyte macrophage-colony stimulating factor, tumour necrosis factor- α and <i>Trypanosoma cruzi</i> infection of murine macrophages," <i>Parasite Immunol.</i> , 17 (3):135-141 (1995). |
| | | Fontt et al., "Granulocyte-Macrophage Colony-Stimulating Factor: Involvement in Control of <i>Trypanosoma cruzi</i> Infection in Mice," <i>Infect. Immun.</i> , 64 (8):3429-3434 (1996). |
| | | Fontt et al., "Effects of Granulocyte-Macrophage Colony-Stimulating Factor and Tumor Necrosis Factor Alpha on <i>Trypanosoma cruzi</i> Trypomastigotes," <i>Infect. Immun.</i> , 66 (6):2722-2727 (June 1998). |
| | | Fouts et al., "Nucleotide sequence and transcription of a trypomastigote surface antigen gene of <i>Trypanosoma cruzi</i> ," <i>Mol. Biochem. Parasitol.</i> , 46 :189-200 (1991). |
| | | Fouts et al., " <i>Trypanosoma cruzi</i> trypomastigote surface glycoprotein (TSA-1) mRNA, GenBank Accession No. M58466," (1993). |
| | | Garg et al., "Proteins with Glycosylphosphatidylinositol (GPI) Signal Sequences Have Divergent Fates during a GPI Deficiency," <i>J. Biol. Chem.</i> , 272 (19):12482-12491 (1997). |
| | | Garg et al., "Delivery by <i>Trypanosoma cruzi</i> of Proteins into the MHC Class I Antigen Processing and Presentation Pathway," <i>J. Immunol.</i> , 158 :3293-3302 (1997). |
| | | Garg et al., "Elicitation of protective immunity to <i>Trypanosoma cruzi</i> using DNA vaccines," Proceedings of the 10 th International Congress of Immunology, New Delhi, India, Monduzzi, Bologna pages 1421-1426 (November 1-6, 1998). |

| | |
|--|------------------------|
| EXAMINER | Date Considered |
| <small>*Examiner: Initial if reference considered, whether or not citation is in conformance with MPEP 609; Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.</small> | |

| | | | |
|---|--|--|-------------------------------|
| INFORMATION DISCLOSURE STATEMENT | | Atty. Docket No.: 235.0020 0101 | Serial No.: 09/518,156 |
| | | | |
| Applicant(s): TARLETON et al. | | | |
| | | Filing Date: 2 March 2000 | Group: Unassigned |

OCT 04 2000

PATENT & TRADEMARK OFFICE

| | | |
|--|--|---|
| | | Geissler et al., "Enhancement of Cellular and Humoral Immune Responses to Hepatitis C Virus Core Protein Using DNA-Based Vaccines Augmented with Cytokine-Expressing Plasmids," <i>J. Immunol.</i> , <u>158</u> (3):1231-1237 (1997). |
| | | Gomes, "PCR and Sero-Diagnosis of Chronic Chagas' Disease," <i>Appl. Biochem. Biotechnol.</i> , <u>66</u> (2):107-119 (1997). |
| | | Gurunathan et al., "Vaccination with DNA Encoding the Immunodominant LACK Parasite Antigen Confers Protective Immunity to Mice Infected with <i>Leishmania major</i> ," <i>J. Exp. Med.</i> , <u>186</u> (7):1137-1147 (1997). |
| | | Ha et al., "Use of the green fluorescent protein as a marker in transfected <i>Leishmania</i> ," <i>Mol. Biochem. Parasitol.</i> , <u>77</u> :57-64 (1996). |
| | | Hartikka et al., "An Improved Plasmid DNA Expression Vector for Direct Injection into Skeletal Muscle," <i>Human Gene Ther.</i> , <u>7</u> (10):1205-1217 (1996). |
| | | Hoffman et al., "Toward clinical trials of DNA vaccines against malaria," <i>Immunol. Cell Biol.</i> , <u>75</u> (4):376-381 (1997). |
| | | Hsu et al., "Immunoprophylaxis of allergen-induced immunoglobulin E synthesis and airway hyperresponsiveness <i>in vivo</i> by genetic immunization," <i>Nat. Med.</i> , <u>2</u> (5):540-544 (1996). |
| | | Hudson et al., "Immune response to South American trypanosomiasis and its relationship to Chagas' disease," <i>Brit. Med. Bull.</i> , <u>41</u> (2):175-180 (1985). |
| | | Iida et al., "Amastigotes of <i>Trypanosoma cruzi</i> escape destruction by the terminal complement components," <i>J. Exp. Med.</i> , <u>169</u> :881-891 (1989). |
| | | Inverso et al., " <i>Crithidia fasciculata</i> contains a transcribed leishmanial surface proteinase (gp63) gene homologue," <i>Mol. Biochem. Parasitol.</i> , <u>57</u> :47-54 (1993). |
| | | Irvine et al., "Cytokine Enhancement of DNA Immunization Leads to Effective Treatment of Established Pulmonary Metastases," <i>J. Immunol.</i> , <u>156</u> (1):238-245 (1996). |
| | | Jones et al., "Amplification of a <i>Trypanosoma cruzi</i> DNA sequence from inflammatory lesions in human chagasic cardiomyopathy," <i>Am. J. Trop. Med. Hyg.</i> , <u>48</u> (3):348-357 (1993). |
| | | Jones et al., "Synthetic oligodeoxynucleotides containing CpG motifs enhance immunogenicity of a peptide malaria vaccine in <i>Aotus</i> monkeys," <i>Vaccine</i> , <u>17</u> (23-24):3065-3071 (August 6, 1999). |

| | |
|-----------------|------------------------|
| EXAMINER | Date Considered |
|-----------------|------------------------|

*Examiner: Initial if reference considered, whether or not citation is in conformance with MPEP 609; Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

| | | | |
|---|--|--|-------------------------------|
| INFORMATION DISCLOSURE STATEMENT | | Atty. Docket No.: 235.0020 0101 | Serial No.: 09/518,156 |
| | | | |
| Applicant(s): TARLETON et al. | | | |
| Filing Date: 2 March 2000 | | Group: Unassigned | |

OCT 04 2000

PATENT & TRADEMARK OFFICE

| | | |
|--|--|--|
| | | Kelly et al., "A shuttle vector which facilitates the expression of transfected genes in <i>Trypanosoma cruzi</i> and <i>Leishmania</i> ," <u>Nuc. Acids Res.</u> , <u>20</u> (15):3963-3969 (1992) |
| | | Kelly, "Trypanosomatid Shuttle Vectors: New Tools for the Functional Dissection of Parasite Genomes," <u>Parasitol. Today</u> , <u>11</u> (12):447-450 (1995). |
| | | Kidder et al., "The Growth and Nutrition of <i>Crithida fasciculata</i> ," <u>J. Gen. Microbiol.</u> , <u>18</u> :621-638 (1958). |
| | | Kierszenbaum and Hudson, "Autoimmunity in Chagas Disease: Cause or Symptom?" <u>Parasitol. Today</u> , <u>1</u> (1):4-9 (1985). |
| | | Kierszenbaum, "Autoimmunity in Chagas' disease," <u>J. Parasitol.</u> , <u>72</u> (2):201-211 (1986). |
| | | Kim et al., "In Vivo Engineering of a Cellular Immune Response by Coadministration of IL-12 Expression Vector with a DNA Immunogen," <u>J. Immunol.</u> , <u>158</u> (2):816-826 (1997). |
| | | Kim et al., "Cytokine Molecular Adjuvants Modulate Immune Responses Induced by DNA Vaccine Constructs for HIV-1 and SIV," <u>J. Interferon Cytokine Res.</u> , <u>19</u> (1):77-84 (January 1999). |
| | | Kozak, "Features in the 5' Non-coding Sequences of Rabbit α and β -Globin mRNAs that Affect Translational Efficiency," <u>J. Mol. Biol.</u> , <u>235</u> :95-110 (1994). |
| | | Krettli et al., "Resistance against <i>Trypanosoma cruzi</i> associated to anti-living trypomastigote antibodies," <u>J. Immunol.</u> , <u>128</u> (5):2009-2012 (1982). |
| | | La Flamme et al., "Expression of mammalian cytokines by <i>Trypanosoma cruzi</i> indicates unique signal sequence requirements and processing," <u>Mol. Biochem. Parasitol.</u> , <u>75</u> :25-31 (1995). |
| | | Lane et al., "Detection of <i>Trypanosoma cruzi</i> with the polymerase chain reaction and in situ hybridization in infected murine cardiac tissue," <u>Am. J. Trop. Med. Hyg.</u> , <u>56</u> (6):588-595 (1997). |
| | | Le Borgne et al., "In Vivo Induction of Specific Cytotoxic T Lymphocytes in Mice and Rhesus Macaques Immunized with DNA Vector Encoding an HIV Epitope Fused with Hepatitis B Surface Antigen," <u>Virology</u> , <u>240</u> (2):304-315 (January 20, 1998). |

| | |
|--|------------------------|
| EXAMINER | Date Considered |
| <small>*Examiner: Initial if reference considered, whether or not citation is in conformance with MPEP 609; Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.</small> | |

| | | | |
|---|--|--|-------------------------------|
| INFORMATION DISCLOSURE STATEMENT | | Atty. Docket No.: 235.0020 0101 | Serial No.: 09/518,156 |
| | | | |
| Applicant(s): TARLETON et al. | | | |
| | | Filing Date: 2 March 2000 | Group: Unassigned |

OCT 04 2000
PATENT & TRADEMARK OFFICE

| | | |
|--|--|--|
| | | LeBowitz et al., "Development of a stable <i>Leishmania</i> expression vector and application to the study of parasite surface antigen genes," <u>Proc. Natl. Acad. Sci. USA</u> , <u>87</u> :9736-9740 (1990). |
| | | LeBowitz et al., "Simultaneous transient expression assays of the trypanosomatid parasite <i>Leishmania</i> using β -galactosidase and β -glucuronidase as reporter enzymes," <u>Gene</u> , <u>103</u> :119-123 (1991). |
| | | Ley et al., "The exit of <i>Trypanosoma cruzi</i> from the phagosome is inhibited by raising the pH of acidic compartments," <u>J. Exp. Med.</u> , <u>171</u> :401-413 (1990). |
| | | Low et al., " <i>Trypanosoma cruzi</i> amastigote surface protein-2 (ASP-2) mRNA, GenBank Accession No. U77951," submitted to Gen Bank on November 11, 1996. |
| | | Low et al., "Molecular cloning of the gene encoding the 83 kDa amstigote surface protein and its identification as a member of the <i>Trypanosoma cruzi</i> sialidase superfamily," <u>Mol. Biochem. Parasitol.</u> , <u>88</u> (1-2):137-149 (1997). |
| | | Low et al., "Amastigote Surface Proteins of <i>Trypanosoma cruzi</i> Are Targets for CD8 $^{+}$ CTL," <u>J. Immunol.</u> , <u>160</u> :1817-1823 (February 15, 1998). |
| | | Lowrie et al., "Protection against tuberculosis by a plasmid DNA vaccine," <u>Vaccine</u> , <u>15</u> (8):834-838 (1997). |
| | | McCluskie et al., "Route and Method of Delivery of DNA Vaccine Influence Immune Responses in Mice and Non-Human Primates," <u>Mol. Med.</u> , <u>5</u> (5):287-300 (May 1999). |
| | | Mensa-Wilmot et al., "A Glycosylphosphatidylinositol (GPI)-Negative Phenotype Produced In <i>Leishmania major</i> by GPI Phospholipase C from <i>Trypanosoma brucei</i> : Topography of Two GPI Pathways," <u>J. Cell Biol.</u> , <u>124</u> (6):935-947 (1994). |
| | | Mensa-Wilmot et al., "Purification and Use of Recombinant Glycosylphosphatidylinositol-Phospholipase C," <u>Methods Enzymol.</u> , <u>250</u> :641-655 (1995). |
| | | Meyer zum Büschenfelde et al., " <i>Trypanosoma cruzi</i> induces strong IL-12 and IL-18 gene expression <i>in vivo</i> : correlation with interferon-gamma (IFN- γ) production," <u>Clin. Exp. Immunol.</u> , <u>110</u> (3):378-385 (1997). |
| | | Monaco, "A molecular model of MHC class-I-restricted antigen processing," <u>Immunol. Today</u> , <u>13</u> (5):173-179 (1992). |

| | |
|-----------------|------------------------|
| EXAMINER | Date Considered |
|-----------------|------------------------|

*Examiner: Initial if reference considered, whether or not citation is in conformance with MPEP 609; Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

| | | | |
|---|--|--|-------------------------------|
| INFORMATION DISCLOSURE STATEMENT | | Atty. Docket No.: 235.0020 0101 | Serial No.: 09/518,156 |
| | | | |
| Applicant(s): TARLETON et al. | | | |
| Filing Date: 2 March 2000 | | Group: Unassigned | |

OCT 04 2000
PATENT & TRADEMARK OFFICE

| | | |
|--|--|---|
| | | Muller et al., "Trypanosoma cruzi: Isolate Dependence in the Induction of Lytic Antibodies in the Mouse and Rabbit," <u>Exp. Parasitol.</u> , 61 :284-293 (1986). |
| | | Nabors et al., "Differential control of IFN-γ and IL-2 production during <i>Trypanosoma cruzi</i> infection," <u>J. Immunol.</u> , 146 (10):3591-3598 (1991). |
| | | Nagahara et al., "Transduction of full-length TAT fusion proteins into mammalian cells: TAT-p27 ^{kip1} induces cell migration," <u>Nature Med.</u> , 4 (12):1449-1452 (December 1998). |
| | | Pan et al., "Amastigote and Epimastigote Stage-Specific Components of <i>Trypanosoma cruzi</i> Characterized by Using Monoclonal Antibodies: Purification and Molecular Characterization of an 83-kilodalton Amastigote Protein," <u>J. Immunol.</u> , 143 (3):1001-1008 (1989). |
| | | Peterson et al., "Cloning of a major surface-antigen gene of <i>Trypanosoma cruzi</i> and identification of a nonapeptide repeat," <u>Nature</u> , 322 :(6079):566-568 (1986). |
| | | Rashid et al., "Roles of Gln81 and Cys80 in catalysis by glycosylphosphatidylinositol-phospholipase C from <i>Trypanosoma brucei</i> ," <u>Eur. J. Biochem.</u> , 264 :914-920 (September 1999). |
| | | Raz et al., "Preferential induction of a Th ₁ immune response and inhibition of specific IgE antibody formation by plasmid DNA immunization," <u>Proc. Nat'l. Acad. Sci. USA</u> , 93 (10):5141-5145 (1996). |
| | | Reed, "In vivo administration of recombinant IFN-γ induces macrophage activation, and prevents acute disease, immune suppression, and death in experimental <i>Trypanosoma cruzi</i> infections," <u>J. Immunol.</u> , 140 (12):4342-4347 (1988). |
| | | Reis et al., "An <i>In Situ</i> Quantitative Immunohistochemical Study of Cytokines and IL-2R ⁺ in Chronic Human Chagasic Myocarditis: Correlation with the Presence of Myocardial <i>Trypanosoma cruzi</i> Antigens," <u>Clin. Immunol. Immunopathol.</u> , 83 (2):165-172 (1997). |
| | | Rodriguez et al., " <i>Trypanosoma cruzi</i> Infection in B-Cell-Deficient Rats," <u>Infect. Immun.</u> , 31 (2):524-529 (1981). |
| | | Rötzschke et al., "Exact prediction of a natural T cell epitope," <u>Eur. J. Immunol.</u> , 21 (10):2891-2894 (1991). |

| | |
|--|------------------------|
| EXAMINER | Date Considered |
| <small>*Examiner: Initial if reference considered, whether or not citation is in conformance with MPEP 609; Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.</small> | |

| | | | |
|---|--|--|-------------------------------|
| INFORMATION DISCLOSURE STATEMENT | | Atty. Docket No.: 235.0020 0101 | Serial No.: 09/518,156 |
| | | | |
| Applicant(s): TARLETON et al. | | | |
| Filing Date: 2 March 2000 | | Group: Unassigned | |

OCT 04 2000
PATENT & TRADEMARK OFFICE

| | | |
|--|--|---|
| | | Ruiz et al., "Monoclonal antibodies against the flagellar fraction of epimastigotes of <i>Trypanosoma cruzi</i> : immunoprotection against metacyclic trypomastigotes obtained by immunization of mice with an affinity-purified antigen," <i>Mol. Biochem. Parasitol.</i> , <u>39</u> :117-125 (1990). |
| | | Santos-Buch et al., "Chapter 8: Pathology of Chagas' Disease," <i>Immunology and Pathogenesis of Trypanosomiasis</i> , Tizard, ed., CRC Press, Boca Raton, Title page, publication page and pages 145-183 (1985). |
| | | Santos et al., " <i>Trypanosoma cruzi</i> surface protein-1 mRNA, GenBank Accession No. U74494," submitted to GenBank on October 15, 1996. |
| | | Santos et al., "The identification and molecular characterization of <i>Trypanosoma cruzi</i> amastigote surface protein-1, a member of the <i>trans</i> -sialidase gene superfamily," <i>Mol. Biochem. Parasitol.</i> , <u>86</u> :1-11 (1997). |
| | | Schenkman et al., "Mucin-like glycoproteins linked to the membrane by glycosylphosphatidylinositol anchor are the major acceptors of sialic acid in a reaction catalyzed by trans-sialidase in metacyclic forms of <i>Trypanosoma cruzi</i> ," <i>Mol. Biochem. Parasitol.</i> , <u>59</u> :293-303 (1993). |
| | | Schirmbeck et al., "DNA Vaccine Primes MHC Class I-Restricted, Simian Virus 40 Large Tumor Antigen-Specific CTL in H-2 ^d Mice That Reject Syngeneic Tumors," <i>J. Immunol.</i> , <u>157</u> (8):3550-3558 (1996). |
| | | Schofield, "Control of Chagas' disease vectors," <i>Brit. Med. Bull.</i> , <u>41</u> (2):187-194 (1985). |
| | | Schutze-Redelmeier et al., "Introduction of Exogenous Antigens into the MHC Class 1 Processing and Presentation Pathway by <i>Drosophila</i> Antennapedia Homeodomain Primes Cytotoxic T Cells In Vivo," <i>J. Immunol.</i> , <u>157</u> :650-655 (1996). |
| | | Schwarze et al., "In Vivo Protein Transduction: Delivery of a Biologically Active Protein into the Mouse," <i>Science</i> , <u>285</u> (5433):1569-1572 (September 3, 1999). |
| | | Scott et al., " ⁷⁵ Se-methionine labelled <i>Trypanosoma cruzi</i> blood trypomastigotes: opsonization by chronic infection serum facilitates killing in spleen and liver," <i>Clin. Exp. Immunol.</i> , <u>48</u> :754-757 (1982). |
| | | Sedegah et al., "Protection against malaria by immunization with plasmid DNA encoding circumsporozoite protein," <i>Proc. Nat'l Acad. Sci. USA</i> , <u>91</u> (21):9866-9870 (1994). |

| | |
|--|------------------------|
| EXAMINER | Date Considered |
| <small>*Examiner: Initial if reference considered, whether or not citation is in conformance with MPEP 609; Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.</small> | |

| | | | |
|---|--|--|-------------------------------|
| INFORMATION DISCLOSURE STATEMENT | | Atty. Docket No.: 235.0020 0101 | Serial No.: 09/518,156 |
| | | | |
| Applicant(s): TARLETON et al. | | | |
| Filing Date: 2 March 2000 | | Group: Unassigned | |

OCT 04 2000
PATENT & TRADEMARK OFFICE

| | | |
|--|--|---|
| | | Seifert et al., "Shuttle mutagenesis: A method of transposon mutagenesis for <i>Saccharomyces cerevisiae</i> ," <u>Proc. Natl. Acad. Sci. USA</u> , <u>83</u> :735-739 (1986). |
| | | Sheibani, "Prokaryotic gene fusion expression systems and their use in structural and functional studies of proteins," <u>Prep. Biochem. Biotechnol.</u> , <u>29</u> (1):77-90 (February 1999). |
| | | Shi et al., "Immunogenicity and <i>in vitro</i> protective efficacy of a recombinant multistage <i>Plasmodium falciparum</i> candidate vaccine," <u>Proc. Natl. Acad. Sci. USA</u> , <u>96</u> (4):1615-1620 (February 16, 1999). |
| | | Silva et al., "Tumor Necrosis Factor Alpha Mediates Resistance to <i>Trypanosoma cruzi</i> Infection in Mice by Inducing Nitric Oxide Production in Infected Gamma Interferon-Activated Macrophages," <u>Infect. Immun.</u> , <u>63</u> (12):4862-4867 (1995). |
| | | Silva et al., "The role of IL-12 in experimental <i>Trypanosoma cruzi</i> infection," <u>Braz. J. Med. Biol. Res.</u> , <u>31</u> (1):111-115 (January 1998). |
| | | Sin et al., "Enhancement of protective humoral (Th2) and cell-mediated (Th1) immune responses against herpes simplex virus-2 through co-delivery of granulocyte-macrophage colony-stimulating factor expression cassettes," <u>Eur. J. Immunol.</u> , <u>28</u> (11):3530-3540 (November 1998). |
| | | Swinkels et al., "A phosphoglycerate kinase-related gene conserved between <i>Trypanosoma brucei</i> and <i>Critchidia fasciculata</i> ," <u>Mol. Biochem Parasitol</u> , <u>50</u> :69-78 (1992). |
| | | Tacket et al., "Phase 1 safety and immune response studies of a DNA vaccine encoding hepatitis B surface antigen delivered by a gene delivery device," <u>Vaccine</u> , <u>17</u> (22):2826-2829 (July 16, 1999). |
| | | Tarleton, "Depletion of CD8 ⁺ T cells increases susceptibility and reverses vaccine-induced immunity in mice infected with <i>Trypanosoma cruzi</i> ," <u>J. Immunol.</u> , <u>144</u> (2):717-724 (1990). |
| | | Tarleton et al., ""Autoimmune rejection" of neonatal heart transplants in experimental Chagas disease is a parasite-specific response to infected host tissue," <u>Proc. Natl. Acad. Sci. USA</u> , <u>94</u> (8):3932-3937 (1997). |
| | | Tarleton et al., "Chagas Disease Etiology: Autoimmunity or Parasite Persistence?" <u>Parasitol. Today</u> , <u>15</u> (3):94-99 (March 1999). |

| | |
|-----------------|------------------------|
| EXAMINER | Date Considered |
|-----------------|------------------------|

*Examiner: Initial if reference considered, whether or not citation is in conformance with MPEP 609; Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

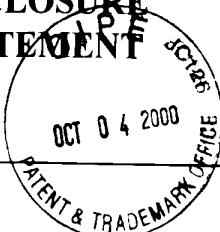
| | | | |
|---|--|--|-------------------------------|
| INFORMATION DISCLOSURE STATEMENT | | Atty. Docket No.: 235.0020 0101 | Serial No.: 09/518,156 |
|  | | | |
| Applicant(s): TARLETON et al. | | | |
| Filing Date: 2 March 2000 | | Group: Unassigned | |

| | | |
|--|--|--|
| | | Tarleton et al., "Vaccine Discovery and Testing in a Murine Model of American Trypanosomiasis," Abstract C10 <u>Mem. Inst. Oswaldo Cruz, Rio de Janeiro</u> , 94 (Suppl. II):17 (November, 1999). |
| | | Teilhet et al., "Effect of short 5' UTRs on protein synthesis in two biological kingdoms," <u>Gene</u> , 222 (1):91-97 (November 5, 1998). |
| | | Tobin et al., "Transfected <i>Leishmania</i> Expressing Biologically Active IFN- γ ," <u>J. Immunol.</u> , 150 (11):5059-5069 (1993). |
| | | Torri et al., "A β -Like DNA Polymerase from the Mitochondrion of the Trypanosomatid <i>Crithidia fasciculata</i> ," <u>J. Biol. Chem.</u> , 269 (11):8165-8171 (1994). |
| | | Trischmann, "Role of cellular immunity in protection against <i>Trypanosoma cruzi</i> in mice," <u>Parasite Immunol.</u> , 6 (6):561-570 (1984). |
| | | Udenfriend et al., "How Glycosyl-Phosphatidylinositol-anchored membrane proteins are made," <u>Ann. Rev. Biochem.</u> , 64 :563-591 (1995). |
| | | Ulmer et al., "Heterologous Protection Against Influenza by Injection of DNA Encoding a Viral Protein," <u>Science</u> , 259 (5102):1745-1749 (1993). |
| | | Ullu et al., "Chapter 7: Trans-splicing in trypanosomatid protozoa," <u>Molecular Biology of Parasitic Protozoa</u> , Smith et al., eds., IRL Press, NY, Title page, publication page, and pages 115-133 (1996). |
| | | Vanhamme et al., "Control of Gene Expression in Trypanosomes," <u>Microbiol. Rev.</u> , 59 (2):223-240 (1995). |
| | | Villalta et al., "Effects of human colony-stimulating factor on the uptake and destruction of a pathogenic parasite (<i>Trypanosoma cruzi</i>) by human neutrophils," <u>J. Immunol.</u> , 137 (5):1703-1707 (1986). |
| | | Voth et al., "Differentially expressed <i>Leishmania major</i> gp63 genes encode cell surface leishmanolysin with distinct signals for glycosylphosphatidylinositol attachment," <u>Mol. Biochem. Parasitol.</u> , 93 (1):31-41 (May 15, 1998). |
| | | Waisman et al., "Suppressive vaccination with DNA encoding a variable region gene of the T-cell receptor prevents autoimmune encephalomyelitis and activates Th2 immunity," <u>Nature Med.</u> , 2 (8):899-905 (1996). |
| | | Wallace, "Flagellate parasites of mosquitos with special reference to <i>Crithidia fasciculata</i> léger 1902," <u>J. Parasitol.</u> , 29 :196-205 (1943). |

| | |
|-----------------|------------------------|
| EXAMINER | Date Considered |
|-----------------|------------------------|

*Examiner: Initial if reference considered, whether or not citation is in conformance with MPEP 609; Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

| | | | |
|---|--|--|-------------------------------|
| INFORMATION DISCLOSURE STATEMENT | | Atty. Docket No.: 235.0020 0101 | Serial No.: 09/518,156 |
| | | | |
| Applicant(s): TARLETON et al. | | | |
| | | Filing Date: 2 March 2000 | Group: Unassigned |



| | | |
|--|--|--|
| | | Wang et al., "Simultaneous Induction of Multiple Antigen-Specific Cytotoxic T Lymphocytes in Nonhuman Primates by Immunization with a Mixture of Four <i>Plasmodium falciparum</i> DNA Plasmids," <i>Infect. Immun.</i> , 66 (9):4193-4202 (September, 1998). |
| | | Wang et al., "Induction of Antigen-Specific Cytotoxic T Lymphocytes in Humans by a Malaria DNA Vaccine," <i>Science</i> , 282 :476-480 (October 16, 1998). |
| | | Wirtz et al., "Inducible Gene Expression in Trypanosomes Mediated by a Prokaryotic Repressor," <i>Science</i> , 268 :1179-1183 (1995). |
| | | Wirtz et al., "Regulated processive transcription of chromatin by T7 RNA polymerase in <i>Trypanosoma brucei</i> ," <i>Nuc. Acids Res.</i> , 26 (20):4626-4634 (October 15, 1998). |
| | | Wirtz et al., "A tightly regulated inducible expression system for conditional gene knock-outs and dominant-negative genetics in <i>Trypanosoma brucei</i> " <i>Mol. Biochem. Parasitol.</i> , 99 (1):89-101 (March 15, 1999). |
| | | Wizel et al., "Induction of murine cytotoxic T lymphocytes against <i>Plasmodium falciparum</i> sporozoite surface protein 2," <i>Eur. J. Immunol.</i> , 24 (7):1487-1495 (1994). |
| | | Wizel et al., "Identification of <i>Trypanosoma cruzi</i> Trans-Sialidase Family Members as Targets of Protective CD8 ⁺ TC1 Responses," <i>J. Immunol.</i> , 159 (12):6120-6130 (1997). |
| | | Wizel et al., "Human Infection with <i>Trypanosoma cruzi</i> Induces Parasite Antigen-Specific Cytotoxic T Lymphocyte Responses," <i>J. Clin. Invest.</i> , 102 (5):1062-1071 (September 1998). |
| | | Wizel et al., "Vaccination with Trypomastigote Surface Antigen 1-Encoding Plasmid DNA Confers Protection against Lethal <i>Trypanosoma cruzi</i> Infection," <i>Infect. Immun.</i> , 66 (11):5073-5081 (November 1998). |
| | | Wrightsman et al., "Identification of Immunodependent Epitopes in <i>Trypanosoma cruzi</i> Trypomastigone Surface Antigen-1 Protein That Mask Protective Epitopes," <i>J. Immunol.</i> , 153 (7):3148-3154 (1994). |
| | | Xiang et al., "Vaccination with a Plasmid Vector Carrying the Rabies Virus Glycoprotein Gene Induces Protective Immunity against Rabies Virus," <i>Virology</i> , 199 (1):132-140 (1994). |

| | |
|-----------------|------------------------|
| EXAMINER | Date Considered |
|-----------------|------------------------|

*Examiner: Initial if reference considered, whether or not citation is in conformance with MPEP 609; Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

| | | | |
|---|--|--|-------------------------------|
| INFORMATION DISCLOSURE STATEMENT | | Atty. Docket No.: 235.0020 0101 | Serial No.: 09/518,156 |
| | | | |
| Applicant(s): TARLETON et al. | | | |
| Filing Date: 2 March 2000 | | Group: Unassigned | |

OCT 04 2000
JCLB
PATENT & TRADEMARK OFFICE

| | | |
|-----------------|--|--|
| | | Xiang et al., "Manipulation of the Immune Response to a Plasmid-Encoded Viral Antigen by Coinoculation with Plasmids Expressing Cytokines," <u>Immunity</u> , 2(2):129-135 (1995). |
| | | Yokoyama et al., "DNA Immunization Confers Protection against Lethal Lymphocytic Choriomeningitis Virus Infection," <u>J. Virol.</u> , 69(4):2684-2688 (1995). |
| | | Zhang et al., "The expression of biologically active human p53 in <i>Leishmania</i> cells: a novel eukaryotic system to produce recombinant proteins," <u>Nuc. Acids Res.</u> , 23(20):4073-4080 (1995). |
| | | Zhang et al., "Identification and overexpression of the A2 amastigote-specific protein in <i>Leishmania donovani</i> ," <u>Mol. Biochem. Parasitol.</u> , 78:79-90 (1996). |
| | | Zhang et al., "Loss of virulence in <i>Leishmania donovani</i> deficient in an amastigote-specific protein, A2," <u>Proc. Natl. Acad. Sci. USA</u> , 94:8807-8811 (1997). |
| EXAMINER | | Date Considered |

*Examiner: Initial if citation considered, whether or not citation is in conformance with MPEP 609; Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

Based on Form PTO-FB-A820 Patent and Trademark Office, U.S. Department of Commerce
(Also form PTO-1449)

RECEIVED

**INFORMATION
DISCLOSURE
STATEMENT**

Atty. Docket No.: 235.0020 0101

Serial No.: 09/15,596

Applicant(s): TARLETON et al.

NOV 03 2000
16-15

Filing Date: 2 March 2000

Group: Unassigned
TECH CENTER 1600/2000

OCT 30 2000 C8

U.S. PATENT DOCUMENTS

| Examiner Initial | TRADEMARK OFFICE Document Number | Date | Name | Class | SubClass | Filing Date If Appropriate |
|------------------|----------------------------------|------|------|-------|----------|----------------------------|
| | NONE | | | | | |

FOREIGN PATENT DOCUMENTS

| | Document Number | Date | Country | Class | SubClass | Translation |
|--|-----------------|------|---------|-------|----------|-------------|
| | NONE | | | | | Yes |
| | | | | | | No |

OTHER DOCUMENTS (Including Authors, Title, Date, Pertinent Papers, etc.)

| | |
|---|--|
| ~ | Higuchi et al., "The Role of Active Myocarditis in the Development of Heart Failure in Chronic Chagas' Disease: A Study Based on Endomyocardial Biopsies," <u>Clin. Cardiol.</u> 10(11):665-670 (1987). |
| ~ | Low et al., "Identification of the 83-kDa Amastigote Surface Protein of Trypanosoma cruzi as a Member of the Sialidase Family and a Target of CTL Responses," Abstract and Poster, Joint Meeting of the Amer. Soc. Tropical Med. Hyg., Amer. Soc. Parasitologists, Baltimore, MD 6 pages (1996). |
| ~ | Santos et al., "The Identification and Molecular Characterization of a Trypanosoma cruzi Amastigote Surface Protein, Asp-1, a Member of the Trans-Sialidase Gene Superfamily," Abstract and Poster, Joint Meeting of the Amer. Soc. Biochemistry and Molecular Biology, Amer. Soc. Investigative Pathology, and Amer. Assoc. Immunologists, June 1-6, New Orleans, LA, <u>FASEB J.</u> , 10(6):A1083 9 pages (1996). |
| ~ | World Health Organization, "Special programme for research and training in tropical diseases, Sixth Programme Report, Chapter Six: Chagas' Disease," TDR/PR-6/83.6 - CHA, UNDP/World Bank/WHO (1983). |
| ~ | World Health Organization, "Special programme for research and training in tropical diseases; Meeting on the development of trypanocidal compounds for the sterilization of blood," Geneva, December 13-14, TDR/CHA/BS/84.3, UNDP/World Bank/WHO (1984). |

EXAMINER

MARK

NAWALI

Date Considered

6/16/03

*Examiner: Initial if citation considered, whether or not citation is in conformance with MPEP 609; Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.